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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/774,043

02/05/2004

Maheer N. Qabbar

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12/03/2008

MYRIAD GENETICS INC.
INTELLECUTAL PROPERTY DEPARTMENT
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SALT LAKE CITY, UT 84108

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/774,043

Applicant(s)

QABAR ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-14 and 30-53 is/are pending in the application.
- 4a) Of the above claim(s) 30-32, 34-45 and 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14, 33, 46, 47, 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicants' Amendment filed August 28, 2008 is acknowledged. Claims 10-14 and 30-53 are pending. Elections were made without traverse on March 7, 2008 of Group II, drawn to methods of inhibiting a kinase, and, as the elected specie, the compound of claim 33.

Methods of inhibiting a kinase comprising administering the compound of instant claim 33 remain under consideration, claims 10-14, 33, 46, 47 and 53. Those methods of use comprising administering compounds other than that of instant claim 33, and claims 30-32, 34-45 and 48-52, remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions.

In response to a request for a complete list of co-pending and related applications set forth in the first Office Action, Applicants supplied the priority history of the present application. A complete list of co-pending and related applications for present inventive entity is again requested when responding to this Office Action.

An amended Abstract is noted.

Those objections and rejections not herein reiterated are hereby withdrawn. The following rejections constitute the only rejections presently applied to the instant claims.

Claims 10-14, 33, 46 and 53 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 30 of U.S. Patent No. 7,053,214. It was asserted the claims are not patentably distinct from each other because claim 30 in the patent is drawn to the treatment of ulcerative colitis, an inflammatory disorder, comprising administering a compound of the structure of claim 1. The compound of instant claim 10 is encompassed in claim one.

Applicants argue the instant application is "earlier in time" and there is no potential for unjustified extension of patent term.

An assertion that the instant application is "earlier in time" is without merit. Because there is a potential for unjustified extension of patent term, the rejection of record on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 30 of U.S. Patent No. 7,053,214 is maintained.

Claims 46 and 47 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, and, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 46 recites "treatment of cancer, angiogenesis, restenosis, edema, inflammation, asthma and arthritis." It was asserted there is insufficient written description for this claim limitation in the disclosure.

Applicants cite the USPTO Revised Interim Utility Guideline Training Material, page 5, and various articles presented as Exhibits A-F to show that kinase inhibitors are known in the prior art to treat diseases.

There is no question kinase inhibition is a therapeutic target in the treatment of various diseases. However, in the present application there is no description in the disclosure of critical parameters or working examples that would lead one skilled in the medical art to immediately envisage administering the specific compound of instant

claim 33 in a treatment modality for any cancer, any pathology characterized by angiogenesis, restenosis, edema or inflammation, asthma and arthritis.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

Adequate description requires more than a mere statement that treatment of cancer, angiogenesis, restenosis, edema, inflammation, asthma and arthritis is part of the invention. *Genetech Inc. vs. Nova Nordisk* states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit, 1997).

It is not clear Applicants were in possession of the full scope of the claimed methods at the time the invention was made. There is no reasonable expectation of success based merely on a showing of anti-thrombotic activity or protease inhibition. The amount of experimentation to practice the claimed method would be unduly extensive. Accordingly, the rejection of record of claims 46 and 47 under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614

November 29, 2008